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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------------------------------------------------------------------------------------|-------------|----------------------|---------------------|------------------|
| 09/695,116 | 10/24/2000 | Vivek Thappa | THA-P-00-001 | 4881 |
| 7590 06/30/2004 | | | EXAMINER | |
| Patents+TMS A Professional Corporation Third Floor 1914 N. Milwaukee Avenue Chicago, IL 60647 | | | MAIORINO, ROZ | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3763 | |
| DATE MAILED: 06/30/2004 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/695,116

Applicant(s)

THAPPA, VIVEK

Examiner

Roz Maiorino

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3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 22 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7-11, 15-20, 23, 24 and 26 is/are allowed.
- 6) ☒ Claim(s) 1-6, 12-13, 21-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Claim Objections***

1. Claims 1-6, 12-13 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Applicant in his claims has refereed to a top end, however such a limitation is no were in the specification and the examiner has always interpreted the top end to mean the proximal end of the catheter since the bottom end in the specification is referring to the distal end of the catheter 104. however with the new amendments it is no at all clear what the bottom or the top end is referring to. The specification refers to a bottom end 104 as shown in figure 2 the bottom end is the distal end of the catheter 102 however the applicant is claiming the bottom end has a different diameter than the catheter so he must be referring to item 204 in figure 3 and not 104 in figure 2 as indicated by the specification and the drawings. However that still does not explain what the top end is?

Furthermore the new amendment referees to a first end and a second end, besides the fact that such a description does not exists in the specification and the introduction of such language is deemed new matter, it is not clear how the fist and second end differ from the top and the bottom end.

Additionally, the applicant has introduced a first part and a second part of the cylinder which again is NOT in the specification, however first and second

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elements are and hence the examine has interpreted the first and the second end of the cylinder to be the same as the first and second part in the claim.

The applicant also claims the second part forms a cross, however it is not clear what the cross is referring to since no such thing is in the specification or the drawings, hence even the introduction of such language is deemed new matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-6, 12-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant has amended the claims to read on a first and second end, however no such description existed in the specification or the original claims. Furthermore the applicant is also claiming a second and first part where the second part forms a cross. No such description of a first and second part existed in the specification or the original claims, furthermore no description of a second part forming a cross existed in the specification or the original claims.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-6, 12-14 and 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6059802 to Ginn, and further in view of U.S. Patent No. 5360414 to Yarger.

Ginn teaches a catheter introducer comprising of a cylindrical body defining a cross with a length deigned between a pointed end 26 and a flat end 30. A first part 24 and a second part 22, wherein the first and second part defines the cylindrical body. Locking mechanism figs 6-7 where the first part and the removable second part are locked together. The pointed end of the cylindrical body gradually tapers to the cylindrical portions. A recess portion 40 along the length of the first portion 22 and a protruding element 42 defined in shaped by a right angle located along the recessed portion of the first part. The recess portion 40 may readily accept the protrusion 42 along the length of the removable second part. A first hole 78 located a distance from the pointed end of the cylinder. A leg 66 attached to the bottom end of the cylinder. A second hole 70 located on the leg of the cylinder and a thread connected (locking mechanism) 80 and 74 to the cylinder form the second hole to the first hole. A groove or

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plurality of holes 38 cut into the cylinder. Ginn does not teach a catheter with two notches located a distance from each other.

Yarger teaches a catheter (tube) with two notches 28a distance from each other with a locking mechanism 24 located on the bottom end of the flexible body. The tube also comprises of multiple holes 28b.

Therefore it would have been obvious to one having ordinary skill in the art to have used the catheter introducer of Ginn for the introduction of a catheter or tube such as Yarger, because its well known in the art that any tube or catheter needs an introducer for guidance and maneuvering into the body.

Allowable Subject Matter

4. Claims 7-11, 23-24, 15-20 allowed.

The following is a statement of reasons for the indication of allowable subject matter: the method of introducing a catheter via a catheter introducer where the introducer pierces the skin and the subcutaneous layer and the cylindrical body is pushed in and is exposed to an outside exit site of the body; and the second part of the cylinder of the introducer catheter is removed attaching a notch of the flexible hollow body of the catheter to the first part of the cylindrical body of the introducer catheter.

Response to Arguments

5. Applicant's arguments filed 3-22-2004 have been fully considered but they are not persuasive. The amended claims are confusing and add new matter, hence they do not overcome the previous rejection.

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Conclusion

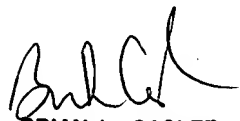
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roz Maiorino whose telephone number is 703-305-2336. The examiner can normally be reached on 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



RM


BRIAN I. CASLER
SUPERVISOR EXAMINER
703-308-3552